

DOCKET NO.: C1037.70045US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Krieg et al.

Serial No.:

10/613,228

Confirmation No.:

4680

Filed:

July 3, 2003

For:

NUCLEIC ACID COMPOSITIONS FOR STIMULATING IMMUNE RESPONSES

Examiner:

Nita M. Minnifield

Art Unit:

1645

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the _______ day of December, 2006.

Emily E. **Zu**kauska

MAIL STOP AMENDMENT

Commissioner For Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir

Transmitted herewith are the following documents:

- Information Disclosure Statement
- PTO Form 1449 with cited references
- Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

A check in the amount of \$180 is enclosed to cover the filing fee. If the fee is insufficient, the balance may be charged to Deposit Account 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,

By:

Maria A. Trevisan, Reg. No.: 48,207 Wolf, Greenfield & Sacks, P.C.

600 Atlantic Avenue

Boston, Massachusetts 02210-2206

Telephone: (617) 646-8000

Docket No.: C1037.70045US00 Date: December **6**, 2006

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Emily E. Zukauskas

MAIL STOP AMENDMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

STATEMENT FILED PURSUANT TO THE DUTY OF DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed more than three months after the filing date of this application and after the mailing date of the first Office action, but before the mailing date of any final action under 37 C.F.R. §1.113, a Notice of Allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in this application.

The fee of \$180.00 as set forth in 37 C.F.R. §1.17(p) is enclosed.

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Conf. No.: 4680

PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified PTO/SB/08). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

The Applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application:

Serial No.	Filing Date	Inventor(s)	Docket No.
11/595,823	11-10-2006	Wagner et al.	*C1041.70035US01
11/598,207	11-10-2006	Krieg et al.	*C1039.70048US24

^{*}A copy of this reference is not provided as the Office has waived the requirement under 37 C.F.R. 1.98(a)(2)(iii) for submitting a copy of a cited U.S. patent application if it is scanned to the Image File Wrapper system and is available on Private PAIR.

PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

- 1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
- 2. The enclosed form PTO-1449 (modified PTO/SB/08) be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
- 3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

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By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his or her own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,

By:

Maria A. Trevisan, Reg. No. 48,207 Wolf, Greenfield & Sacks, P.C.

600 Atlantic Avenue

Boston, Massachusetts 02210-2206

Telephone: (617) 646-8000

Docket No.: C1037.70045US00

Date: December 6, 2006

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OKA 9 A and B (iddified P	TO/SB/08)	APPLICATION NO.:	10/613,228	ATTY. DOCKET NO.: C1037.70045US00
ð	/		FILING DATE:	July 3, 2003	CONFIRMATION NO.: 4680
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1	of	2	GROUP ART UNIT:	1645	EXAMINER: Nita M. Minnifield
	Oka49) A and B (g	Off 191A and B (prodified P) A and B (prodified P) APPL	Off 19 A and B (Bodified PTO/SB/08) MATION DISCLOSURE EMENT BY APPLICANT	APPLICATION NO.: APPLICATION NO.: FILING DATE: APPLICANT: GROUP ART UNIT:	APPLICATION NO.: 10/613,228 APPLICATION NO.: 10/613,228 FILING DATE: July 3, 2003 APPLICANT: Krieg et al. GROUP ART UNIT: 1645

U.S. PATENT DOCUMENTS

Examiner's Initials #	Cite	U.S. Patent Do	cument	Name of Patentee or Applicant of Cited	Date of Publication or Issue	
	No.	Number	Kind Code	Document Document	of Cited Document MM-DD-YYYY	
***	A139	2004-0053880	A1	Krieg	03-18-2004	
	A140	2004-0076905	A1	Yagihashi et al.	04-22-2004	
	A141	2004-0234960	Al	Olek et al.	11-25-2004	
	A142	2005-0019340	Al	Garcon et al.	01-27-2005	
	A143	2005-0038239	A1	Catchpole	02-17-2005	

FOREIGN PATENT DOCUMENTS

	Cite	Foreign Patent Document			Name of Patentee or Applicant of Cited	Date of Publication of	Translation
	No.	Office/ Country	Number	Kind Code	Document	Cited Document MM-DD-YYYY	(Y/N)
	B23	wo	01/22972	A2	Coley Pharmaceuticals, GmbH	04-05-2001	
	 						
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OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials #	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	C59	AGRAWAL et al., Medicinal chemistry and therapeutic potential of CpG DNA. Trends Mol Med. 2002 Mar;8(3):114-21.	
	C60	BALLAS et al., Divergent therapeutic and immunologic effects of oligodeoxynucleotides with distinct CpG motifs. J Immunol. 2001 Nov 1;167(9):4878-86.	
	C61	BITTON et al., Cancer vaccines: a critical review on clinical impact. Curr Opin Mol Ther. 2004 Feb;6(1):17-26. Abstract Only.	
	C62	CHAN et al., CpG-A and CpG-B oligodeoxynucleotides differentially affect the cytokine profile, chemokine receptor expression and T-cell priming function of human plasmacytoid dendritic cells. Blood. 2002;100:50b. Abstract #3666.	
	C63	DAVILA et al., Repeated administration of cytosine-phosphorothiolated guanine-containing oligonucleotides together with peptide/protein immunization results in enhanced CTL responses with anti-tumor activity. J Immunol. 2000 Jul 1;165(1):539-47.	

EXAMINER:	DATE CONSIDERED:

[#] EXAMINER: Initial if reference considered, whether or notcitation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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FORM PTO	DEC 0-1449/A_and B (1 1. 701	PTO SR/08)	APPLICATION NO.:	10/613,228	ATTY. DOCKET NO.: C1037.70045US00
	\%		<i>E</i> */	FILING DATE:	July 3, 2003	CONFIRMATION NO.: 4680
INFORMATION DISCLESSURE STATEMENT BY APPLICANT			APPLICANT:	Krieg et al.		
				GROUP ART UNIT:	1645	EXAMINER: Nita M. Minnifield
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C64	DE GRUJIL et al., Cancer vaccine strategies get bigger and better. Nat Med. 1999 Oct;5(10):1124-5.	
C65	DONNELLY et al., Cancer vaccine targets leukemia. Nat Med. 2003 Nov;9(11):1354-6.	
C66	JAIN et al., Barriers to drug delivery in solid tumors. Scientific American. 1994; 271:58-65.	
C67	KRIEG et al., Mechanisms and therapeutic applications of immune stimulatory CpG DNA. Pharmacol Ther. 1999 Nov;84(2):113-20.	
C68	KRIEG et al., The CpG motif: Implications for clinical immunology. BioDrugs. 1998 Nov 1;10(5):341-6.	-
C69	LIANG et al., Activation of human B cells by phosphorothioate oligodeoxynucleotides. J Clin Invest. 1996 Sep 1;98(5):1119-29.	
C70	LIPFORD et al., CpG-containing synthetic oligonucleotides promote B and cytotoxic T cell responses to protein antigen: a new class of vaccine adjuvants. Eur J Immunol. 1997 Sep;27(9):2340-4.	
	MacFARLANE et al., Unmethylated CpG-containing oligodeoxynucleotides inhibit apoptosis in WEHI 231 B lymphocytes induced by several agents: evidence for blockade of apoptosis at a distal signalling step. Immunology. 1997 Aug;91(4):586-93.	
· C72	ROCHLITZ et al., Gene therapy of cancer. Swiss Med Wkly. 2001 Jan 12;131(1-2):4-9.	
C73	VERMA et al., Gene therapy—promises, problems, and prospects. Nature. 1997 Sep18;389:239-42.	
C74	VILE et al., Cancer gene therapy: hard lessons and new courses. Gene Ther. 2000 Jan;7(1):2-8.	
C75	WEINER et al., The immunobiology and clinical potential of immunostimulatory CpG oligodeoxynucleotides. J Leukoc Biol. 2000 Oct;68(4):455-63.	

^{*}a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. ___, filed ___, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

[NOTE - No copies of U.S. patents, published U.S. patent applications, or pending, unpublished patent applications stored in the USPTO's Image File Wrapper (IFW) system, are included. See 37 CFR §1.98 and 1287OG163. Copies of all other patent(s), publication(s), unpublished, pending U.S. patent applications, or other information listed are provided as required by 37 CFR §1.98 unless 1) such copies were provided in an IDS in an earlier application that complies with 37 CFR §1.98, and 2) the earlier application is relied upon for an earlier filing date under 35 U.S.C. §120.]

EXAMINER:	DATE CONSIDERED:	
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